

DEPARTMENT OF HEALTH AND HUMAN SERVICES

MAR 20 1996

Mr. Matthew G. Kramer  
Director, Product Development  
Agritope, Inc.  
8505 SW Creekside Place  
Beaverton, Oregon 97005

Dear Mr. Kramer:

This is in regard to Agritope's genetically modified tomato line 35-1-N about which you initiated consultations with the Food and Drug Administration (FDA) in September 1994. The new tomato variety has been engineered to have a modified ripening phenotype through fruit-specific expression of a transgene encoding the enzyme S-adenosylmethionine hydrolase.

As part of bringing your consultation with FDA regarding this product to closure, you submitted a summary of the safety and nutritional assessment of the new tomato variety on January 16, 1996. This communication informed FDA of the steps taken by Agritope to ensure that this product complies with the legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment you have conducted, it is our understanding that Agritope has concluded that tomatoes derived from the new variety are not materially different in composition, safety, and other relevant parameters from tomatoes currently on the market and that the genetically modified tomato does not raise issues that would require premarket review or approval by FDA. All materials relevant to this notification have been placed in a file designated BNF0014. This file will be maintained in the Office of Premarket Approval.

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Based on the information Agritope has presented, we have no further questions concerning this product at this time. However, as you are aware, it is Agritope's continued responsibility to ensure that foods marketed by the firm are safe, wholesome and in compliance with all applicable legal and regulatory requirements.

Sincerely,

/S/

Alan M. Rulis, Ph.D.  
Director  
Office of Premarket Approval  
Center for Food Safety and  
Applied Nutrition

cc: HFS-200 HFS-205 HFS-206 HFS-226 HFS-235 HFS-246  
HFS-247 HFS-13 HOFV-221 BNF0014